REMARKS

Claims 1-33 are pending in the application. No claims have been allowed.

INTERVIEW

On June 19, 2007, the undersigned and Examiner Amy T. Lang conducted a telephone interview in which the operation of a working model embodied by the claims of the above-referenced application was explained in detail. Additionally, the undersigned and the Examiner addressed the outstanding objections to the drawings and objections/rejections under 35 U.S.C. § 112 of the claims. The undersigned proposed minor amendments to some of the claims, as described in further detail below, and addressed other issues raised by the Examiner. It was generally agreed that the discussion during the interview and proposed amendments to the claims satisfactorily addressed all of the drawing and § 112 issues raised by the Examiner in the Office Action. The undersigned wishes to thank the Examiner for the courtesies extended during the interview and the helpful suggestions offered by the Examiner.

OBJECTIONS TO DRAWINGS

The Examiner objected to the drawings under 37 CFR § 1.83(a) as not showing the actuation of the blocking mechanism causing the ring to move to a position so that the needle body is enlarged. During the interview, the undersigned explained this feature in detail with reference to the operation of a working device and Figs. 7a-7e of the Application, which also show this feature. To further address the Examiner's concern, the undersigned proposed to amend claim 27 as set forth above, which now calls for the ring moving "to a position which allows at least one area of the needle body to enlarge." New claim 33 further defines the enlargement. It was agreed that the proposed amendments viewed in light of the undersigned's explanation overcame the drawing objection.

CLAIM REJECTIONS 35 U.S.C. § 112

The Examiner rejected claim 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. During the interview, this specific rejection was discussed, and the undersigned proposed to amend claim 12 as has been done by this Amendment. Claim 12 now recites that "the needle body is movably connected with the needle." It was generally agreed during the interview that this amendment overcomes the § 112 rejection.

The Examiner rejected claims 14 and 24 under 35 U.S.C. § 112, second paragraph. Responsive thereto, this rejection was discussed during the telephone interview, and it was agreed that claim 14 as amended overcomes this rejection. Claim 14 now recites that the needle body comprises a magazine housing that contains a plurality of needles. In view of the explanation of the operation of the device provided by the undersigned, it was agreed that amending claim 24 was unnecessary.

Finally, the Examiner rejected claims 31 and 32 under 35 U.S.C. § 112. The Examiner initially thought that the recitation of the needle moving from a resting position to a lancing position multiple times might be inconsistent with a blocking mechanism that prevents reuse of the needle. These two separate functions were explained by the undersigned during the interview, and the Examiner asked that the undersigned provide a written explanation of the same in this Amendment for the record. Amending claims 31 and 32 would then be unnecessary.

First, the specification clearly discloses a needle that can be used multiple times with the lancing aid before the needle body is removed from the lancing aid. For example, Applicants' specification states that it "should advantageously be possible to easily reuse a needle of a lancet system that has been inserted once." Applicants' Specification, ¶ [0012]. In certain particular embodiments disclosed by Applicants, "the blocking mechanism advantageously only prevents a repeated insertion of the lancet system but does not prevent re-use of a needle that has already been inserted . . . ." Id., ¶ [0024]. In other embodiments, "[t]he blocking mechanism changes the needle body in such a manner that after the lancet system has been ejected from the lancing aid, the holding element on the lancing aid can no longer interact with the holding element of the lancet system when it is reinserted." Id., ¶ [0016].

Applicants thus teach a system in which once the lancet system (or needle body) is removed from the lancing aid, it can no longer be used with the lancing aid. For example, in one particular embodiment, the needle body 2a (provided in the form of a magazine containing several needles) depicted in Applicants' Figs. 7a-7e can only be inserted into the lancing aid once. When first inserted, ring 31 moves and allows elastic arms 90 to move outward. Once removed, the needle body 2a cannot be reinserted because the elastic arms block such reinsertion. In this particular embodiment, reuse of the needle(s) is prevented by preventing reinsertion of the needle body into the lancing aid. In other embodiments, the needle body may be reinserted, but the interaction of the holding elements is prevented, which thereby prevents reuse of the needle.

Applicants' claims are thus perfectly consistent with a blocking mechanism which

prevents reuse of a lancet system after the same is removed from the lancing aid, but which allows a needle to be reused multiple times before it is removed from the lancing aid.

CLAIM REJECTIONS 35 U.S.C. § 102

At the onset, Applicants believe that the explanation of Applicants' claims and supporting disclosure that was given by the undersigned during the telephone interview with the Examiner likely resolved the § 102 and § 103 issues. However, since those issues were not discussed during the interview, Applicants have responded to them below.

The Examiner rejected claims 1-8, 10-12, 13, 14, 16-25 and 29-32 under 35 U.S.C. § 102(c) as being anticipated by U.S. Publication No. 20050015020 to LeVaughn ("LeVaughn").

LeVaughn discloses embodiments of a device for sampling and/or analyzing blood. With reference to Fig. 3 and page 8, ¶ 98 of LeVaughn, cassette 50 is a magazine-like holder for lancets 8 and test elements 10. The cassette can be inserted into the device and removed and discarded after use. A new cassette can then be inserted. The lancet cassette comprises a carrier disk with several lancet elements 172 arranged radially as shown in Fig. 22B. Figs. 19-20 show a plunger 184 and lancet element 172 being held in an operating position by a clamp spring 196 inserted into a holder 194 located between the drive spring 188 and return spring 192. The drive spring 188 is held in a tensioned state until the clamp spring 196 is spread apart and releases the tension. Fig. 27 shows the puncture process, in which the drive spring 188 forces the plunger 184 against the lancet element and drives the lancet 232 (see Fig. 24) radially outward to puncture.

As shown in Figs. 19-28 and described on pages 11-12, ¶ [0112] to ¶ [0116], control lever 202 advances cassette/carrier 178 and lancet element 172 and prevents cassette/carrier 178 from rotating in the reverse direction. See Id., ¶ [0114]. The control lever is turned clockwise as shown in Fig. 21, causing the notched lever 212 to engage tooth rack 216 and rotate carrier part 170 until a new and unused lancet is moved into an operating position. Id., ¶ [0113]. Once the new and unused lancet is in its operating position, the notched lever 212 disengages from the rack 216, thereby preventing further rotation of carrier part 170. Id., ¶ [0114]. At the same time the new and unused lancet is moved into its operating position, rotation of the lever 202 causes cam control surface 204 to engage with and press cam 206 radially inward as shown in Figs. 23-25. Id., ¶ [0115]. As the cam 206 is driven radially inward, the plunger 184 and lancet element 172 move with the cam 206 and energize the drive spring 188 into an armed position. Id., ¶ [0112] and [0116]. Therefore, each time the control lever is rotated clockwise to arm the driving mechanism, a new and unused lancet is

also rotated into its operating position. Furthermore, once the drive spring 188 is energized and the new and unused lancet is in its operating position, the control lever 202 may rotate back to its initial position shown in Fig. 21. Id., ¶ [0112]. When the control lever 202 is rotated counter-clockwise, the notched lever 212 slides across the teeth of the rack 216 and carrier 170 is thus prevented from rotating counter-clockwise. Id., ¶ [0114]. Also, as carrier arm 210 is deflected out of engagement with the carrier part 170, teeth 226 inside the base of housing 178 engage with the teeth of the rack 216 on the carrier 170 to prevent the carrier 170 from rotating counter-clockwise. Id., ¶ [0115].

Thus, LeVaughn teaches a device in which once the lancet is used for puncture, it is automatically advanced and prevented from returning to the active position. Each lancet can thus only be used once while the cassette 50 resides in the housing.

On the other hand, LeVaughn discloses no structure or features that would prevent reinsertion and reuse of a previously used lancet cartridge after it has been removed from the housing. As shown in Figs. 3 and 4 of LeVaughn (reprinted below), cassette 50 includes a first circular disk carrier part 52 for holding test elements 10 and a second carrier part 56 in the form of belt 58 for holding lancets 8. Id., ¶ [0098]. The first carrier part 52 couples to the second carrier part 56 as projections 66 engage with recesses 62. Similarly, the second carrier part 56 couples to a third carrier part 60 through the engagement of recesses 62 and projections 64. Id., ¶ [0098].

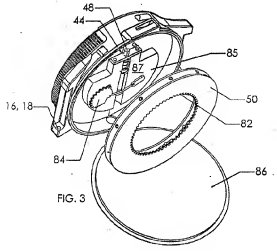

FIG. 3

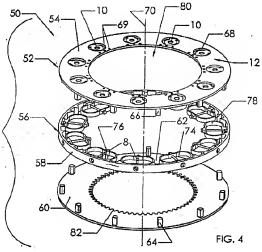

FIG. 4

Once cassette 50 is inserted into housing 4, it is enclosed by a cover part 86. Id., ¶ [0102]. Cassette 50 slides into the housing 4 without changing shape or being reconfigured to prevent reinsertion. The carriers 52, 54, 56 easily couple together to form the cassette 50. There are simply no structural features disclosed by LeVaughn in the cassette 50 that would

prevent its reinsertion after being removed and no structural features that would prevent the needles being reused after such reinsertion.

Applicants respectfully request withdrawal of this rejection because LeVaughn does not identically show all features claimed in Applicants' independent claims 1, 12 and 21. "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference." Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677 (Fed. Cir. 1988).

Claim 1 requires a blocking mechanism that is actuated by an interaction with the lancing aid such that after removal of the lancet system from the lancing aid, reuse of the lancet system with the lancing aid is prevented. Claim 12 calls for a blocking mechanism that is actuated by an interaction with a lancing aid such that reuse of the lancet system with the lancing aid after the lancet system is removed from the lancing aid is prevented. Claim 21 calls for a blocking mechanism, actuation of which changes the shape of the needle body and prevents reuse of the needle with the lancing aid after the needle body is removed from the lancing aid.

First, as just discussed, there is no disclosure in LeVaughn that after its removal, reuse of the lancet system with the lancing aid is prevented, as claimed by Applicants. Thus, LeVaughn does not identically disclose Applicants' claim elements as required to qualify as an anticipating reference under § 102. Applicants therefore respectfully request that the Examiner withdraw all § 102 rejections.

The Examiner appears to be relying on characterizations of the claim terms "lancet system" and "removal" that are inappropriate here. Specifically, the Examiner remarked that "once the needle tip (the lancet system) emerges [past] the housing to puncture the patient, the lancet system has been removed from the housing." Office Action, pg. 5, ¶ 7. However, "ejection" of a lancet tip during a puncture movement is not the same as "removing" a "lancet system" from the lancing aid after use. As Applicants stated in their response of December 15, 2006, the claim term "ejection" was replaced with "removal" for clarity. Further, while the claimed lancet system includes a "needle tip," it includes more than that. As one non-limiting example, in Figs. 7a-7e, the "lancet system" is embodied as a magazine housing having a needle body 2a that includes several needles and their tips. Applicants' specification, ¶ [0060]. Temporary protrusion of a needle tip from the lancet system during a puncture is not the same as "removal of the lancet system from the lancing aid" as claimed by Applicant, and certainly does not meet the requirement of § 102 of identically showing this claimed feature.

The Examiner has also read Applicants' claimed feature of preventing reuse of the

needle with the lancing aid after the needle body is removed onto the control lever 202 of LeVaughn. Office Action, pg. 6, lines 1-4. LeVaughn discloses no such feature. Instead, as discussed above, LeVaughn merely teaches a lancet cassette having multiple lancets in which a used lancet is automatically advanced after it is fired and then cannot be returned to the ready-to-fire position. Applicants' claims do not specifically recite such a feature,[1] and indeed, Applicants' dependent claims 31 and 32 call for a lancet system in which a single needle can be re-used multiple times. This is not possible with the device taught by LeVaughn, which further supports withdrawal of all § 102 rejections over LeVaughn.

Since claims 2-8, 10-11, 13, 14, 16-25 and 29-32 include all of the limitations of claims 1, 12 or 21 as the case may be, it is requested that the § 102 rejections as to these claims be withdrawn as well.

CLAIM REJECTIONS 35 U.S.C. § 103

The Examiner has rejected Applicants' claims 15 and 26-28 as being unpatentable under 35 U.S.C. § 103 (a) over LeVaughn. Claims 15 and 26-28 depend from claims 12 and 21, respectively. As explained above, LeVaughn does not disclose nor even suggest a blocking mechanism as claimed by Applicants in independent claims 12 and 21, and this blocking mechanism is of course also required by dependent claims 15 and 26-28. See In re Fine, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (Board erred by failing to appreciate that the applicant's claims can be distinguished over the cited references). Applicants respectfully request withdrawal of this rejection because there is no suggestion in the LeVaughn reference of Applicant's inventive blocking mechanism.

Furthermore, LeVaughn discloses a device with a cassette that can apparently be reinserted into the housing and the used needles then reused. Thus, instead of blocking reinsertion of the lancet system or cassette or otherwise preventing reuse of the same once removed from the lancing aid, LeVaughn essentially teaches the opposite, thereby teaching away from Applicants' claims. See, e.g., In re Haruna, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (Board erred in finding obviousness when prior art reference taught concealing defects in an outer region of a disk and the claimed design included a transparent outer region in which defects would not be concealed).

Since Levaughn does not teach or suggest a blocking mechanism as required by claims 15 and 26-28, and since LeVaughn actually teaches away from the claimed blocking mechanism, Applicants respectfully request that the Examiner withdraw this rejection.

1 Of course, many of Applicants' claims may read on lancing aids having such a feature. The point is that this feature of LeVaughn is not germane to any of Applicants' claims that do not specifically recite such a feature.

CONCLUSION

Applicants believe that the foregoing is a complete response to the outstanding Office Action and reconsideration is requested. Specifically, Applicants believe that all claims are now in condition for allowance and allowance thereof is earnestly solicited.

In the event Applicants have overlooked the need for a Petition for Extension of Time or payment of fee (except for Issue Fees), Applicants hereby petition therefor and authorize the United States Patent and Trademark Office to charge any additional fees for extension of time to Deposit Account No. 02-3223, Bose McKinney & Evans LLP.

If the Examiner has any questions regarding any of the foregoing, she is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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